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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,071	09/19/2006	Hidetoshi Ito	3712174.00608	3798
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K&L Gates LLP				
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CHICAGO, IL 60690				
EXAMINER				
LACLAIR, DARCY D				
ART UNIT		PAPER NUMBER		
1796				
NOTIFICATION DATE		DELIVERY MODE		
05/03/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary

Application No.

10/599,071

Applicant(s)

ITO ET AL.

Examiner

Darcy D. LaClair

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 10-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 10-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date 2/26/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **1/28/2010** has been entered.

All outstanding rejections, except for those maintained below are withdrawn in light of the amendment filed on **1/28/2010**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 19-20 and 23-24** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to the issue of new matter, **Claims 19, 20, 23 and 24** have been amended to recite the **dry** volume ratio of water-insoluble polymer to monomer having a stimuli-responsive functional group. It is the examiner's position that this is new matter; the specification as originally filed does not support the newly amended term of a dry ratio, and there is no mention of the use of dry ratio on page 12, par 3, where the volume ratio of these two components is discussed. The examples give a dry volume for the polymethyl methacrylate polymer, polystyrene polymer, or poly(vinylidene fluoride) polymer, corresponding to 40% of a volume of acrylic acid. This is not commensurate in scope with the claims for several reasons. First, the only dry volume ratio given in the examples is 40:100, which does not span the broad range given in claims 19 and 23, as it provides a ratio at only a single point. Furthermore, in the entirety of the current claims, nowhere are recited specific polymer species. The only polymer recited as the stimuli-responsive polymer appears to be acrylic acid. Furthermore, in the specification, the water-insoluble polymer is recited as poly(methyl methacrylate), polystyrene, and poly(vinylidene fluoride) (see p. 11, par 2). The stimuli-responsive polymer added as a monomer is acrylic acid, *inter alia*. (See p. 10). Claims 20 and 24 recite the water-insoluble polymer is 100 and the stimuli responsive monomer is 10 to 60. In the examples, the ratio is 0.4 mL of water-insoluble polymer, and 1 mL of stimuli responsive polymer (or 40:100). This does not fall within the instantly claimed range given in Claims 20 or 24, and therefore it does not appear to constitute an example of the instant claims.

3. **Claims 8, 11, 14 and 18** are rejected under 35 U.S.C. 102(b) as being anticipated by **Wu et al. (US 2002/0001571)**.

The rejection of Claims 8, 11 and 14 is adequately set forth in **paragraph 2** of the office action mailed **3/20/2009**, and **paragraph 3** of the office action mailed **10/29/2009**, and is incorporated here by reference.

Claim Rejections - 35 USC § 103

4. **Claims 8 and 10-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Turner et al. (US 6,331,578)**.

The rejection is adequately set forth in **paragraph 5** and **paragraph 6** of the office action mailed **3/20/2009**, and **paragraph 6** of the office action mailed **10/29/2009**, and is incorporated here by reference.

With regard to the amendment to Claims 19-20 and 23-24, requiring the dry volume ratio, Turner teaches that the hydrophobic to hydrophilic ratio in the **dry material** (or in the non-swelled state), in a preferred embodiment, varies from 9:1 to 1:9, more typically in the range of 8:2 to 5:5. (See col 12 line 41-52) This is consistent with a ratio of water-insoluble polymer (hydrophobic) to stimuli-responsive component (hydrophilic) of 100:1.11 to 100:90, more typically 100:25 to 100:100. This encompasses and/or overlaps with applicant's instantly claimed ranges. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74

USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974)

Response to Arguments

5. Applicant's arguments filed **1/28/2010** have been fully considered. Specifically, applicant argues

(A) Applicants have amended Claims 19-20 and 23-34 to recite that the volume ratio is calculated on a dry volume, or unswollen state. Support is noted in the Examples, which recite dry volume ratios of 0.40 mL of the water insoluble polymer PMMA to 1 mL of acrylic acid. (See paragraphs [0060],[0067]), and [0073])

(B) Claims 8 and 14 require that a stimuli responsive hydrogel is comprised of a stimuli-responsive polymer and a water-insoluble polymer. Wu does not even meet this simple combination of two materials. Wu teaches that the stimuli-responsive particles form a hydrogel separate from the water-insoluble membrane.

(C) The independent claims require that the water-insoluble polymer is a polymer without a cross-linking point. Cleary describes the "hydrophobic polymer" as crosslinked. (See Cleary [0059]) Furthermore, the office relies on the plasticizer as a non-crosslinked polymer. Applicants assert that these elements have been taken out of context. Furthermore, the styrene plasticizer contains diene which would serve as a crosslinking point.

(D) Claims 10, 15, 17, and 19-22 are rejected by Cleary with evidence from Kraton Labels (2009). Applicant's question the validity of this reference, as none of the compounds cited by trade name in Cleary correspond to the polymer described by Kraton. However, applicants point out that SIS is styrene-isoprene-styrene, which has a diene that serves as a crosslinking point.

(E) Turner discusses semi-interpenetrating networks where one or more of the polymer components remains linear; the Office relies on this statement to conform that one of ordinary skill in the art would prepare one of those networks. Turner neither makes the claimed invention obvious nor provides an enabling disclosure for the proposed invention. Turner very specifically describes crosslinking of the hydrophobic polymer network, clearly teaching that crosslinking is required to control the nature of the IPNs created in it.

6. **With respect to argument (A)**, applicant's arguments have been considered and the 112 second paragraph rejection has been withdrawn *in light of applicant's amendment*. However note the new matter rejection set forth above, in paragraph 2.

With respect to argument (B), applicant's arguments have been considered but are *not persuasive*. Wu teaches a composite polymer system comprising stimuli-responsive particles and at least one other polymer. The second polymer acts as a matrix. (See par [0012]) This is consistent with a combination in a hydrogel system. Clearly, Wu DOES teach this simple combination in a composite polymer.

With respect to argument (C) and (D), applicant's arguments have been considered, but are moot in view of the rejection set forth above.

With respect to argument (E), applicant's arguments have been considered but are **not persuasive**. Turner teaches that a preferred embodiment of the present invention is preparation of bicontinuous hydrophilic-hydrophobic IPN membranes having a uniform composition, where the hydrophobic component is the host network and the hydrophilic component is the guest network. (See col 9 line 12-20) Turner teaches that semi-IPNs can be prepared in which one or more of the polymer components remains linear. (See col 9 line 30-31) Turner discloses that the host polymer network is preferably the hydrophobic (water insoluble) component in order to provide strength and structure. Additionally, as the hydrophobic host network, Turner teaches polystyrene, which is one of applicant's water-insoluble polymer types. (See col 9 line 48) Upon polymerizing styrene monomers, the polystyrene would not have diene crosslinking points. Furthermore, the functionality of a hydrophilic hydrogel polymer is based in the crosslinked structure which allows the polymer to expand to many times the dry size. While Turner does not explicitly disclose which of the components remains linear, it would be obvious to one of ordinary skill in the art that the hydrophobic polymer would be the component selected as the linear component in the semi-IPN (or that which is not crosslinked). Therefore it would be obvious to one of ordinary skill in the art, when working with a hydrogel system, to employ the hydrophobic component as the linear (or un-crosslinked) component. A linear, or un-crosslinked component, as it is not crosslinkable, would not be crosslinked. Based on the teachings of Turner, an

embodiment and polymer selection is clearly taught, and motivation to use such an embodiment is present. Additionally, while does not exemplify this particular semi-IPN, this does not negate a finding of obviousness under 35 USC 103 since a preferred embodiment such as an example is not controlling. Rather, all disclosures "including unpreferred embodiments" must be considered. *In re Lamberti* 192 USPQ 278, 280 (CCPA 1976) citing *In re Mills* 176 USPQ 196 (CCPA 1972). Therefore, it would have been obvious to one of ordinary skill in the art to prepare a semi-IPN given that Turner teaches each one.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darcy D. LaClair whose telephone number is (571)270-5462. The examiner can normally be reached on Monday-Friday 8:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Milton I. Cano/
Supervisory Patent Examiner, Art Unit 1796

Darcy D. LaClair
Examiner
Art Unit 1796

/DDL/